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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MILLER, CHERYL L

ART UNIT

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3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,153	Applicant(s) CHOBOTOV, MICHAEL V.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18, 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-18 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Fogarty (US 6,123,722) does not disclose the second graft completely overlapping the first graft. The examiner disagrees. As for the product claims, the applicant has claimed separate components configured for overlapping one another. Thus Fogarty's graft need only be capable of a completely overlapped position, which Fogarty's components are.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Referring to claims 9 and 11, the applicant has claimed "deploying the second thin graft member completely within the longitudinal lumen of the deployed first thin graft member". Support was not found for the second member to be completely contained within the first member. Figure 6 shows the second inner graft extending outside of the first graft on one side (inflow end) and in figure 7, the second inner graft is shown to extend outside of the first graft on all ends. No embodiment shown or disclosed describes the inner graft to be shorter to be contained completely within the first graft. Claims 10 and 12-13 depend upon claims 9 and 11 and inherit all problems associated with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite at, "in portions of the graft where at least two of the thin wall graft members are completely overlapped". It is unclear if applicant is claiming the grafts to be partially overlapped ("in portions") or fully overlapped ("completely overlapped"). It seems both are claimed and thus indefinite. Claims 4-8 depend upon claim 1 and inherit all problems with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-5, 7-8, 14-15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (US 6,123,722, cited previously). Fogarty discloses an endovascular graft or kit (60, 90) comprising a plurality of separate thin walled graft members (62, 64, 66; 92, 94) configured to be layered (Fogarty's graft are *capable of* being layered; see figs.3-5). Fogarty discloses two or three graft members, together being able to support a body lumen (col.3, lines 56-65). Fogarty's graft members are *configured* to completely overlap (discloses tailoring overlap range to meet needs of patient; col.3, lines 14-37; col.4, lines 13-18). Fogarty discloses one of the graft members (64 for example in fig.3 or 94 in fig.4, *configured to be placed* on the inner most location) having the greatest length. Fogarty discloses the graft members to be capable of being delivered individually (fig.5; col.6, lines 55-68). Fogarty discloses anchoring mechanisms (barbs 83 or flare seen in fig.6c) on the ends of the graft members. Fogarty's "desired amount" of support in the overlapping graft areas is the amount of support provided by two graft members, and inherently the one graft would not provide the "desired amount", since in the area of overlap, there are 2 grafts and thus the "desired amount" of Fogarty in the overlapping area is the amount of support provided by two grafts, not one. Also, each member is a stent-graft, and the graft members alone do not provide the support to the vessel, it is the stent that provides the support to the graft and to the vessel (col.6, lines 2-6; col.9, lines 7-8), and therefore, all grafts used alone would not provide sufficient strength to hold open the vessel.

Claims 1, 4, 5, 7, 8, 14, 15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Marcade (US 5,683,449). Marcade discloses a endovascular graft kit (fig.2) comprising a plurality of separate thin wall graft members (152 of 110, 112, 114, and 116) configured to be layered, the graft members *configured* to have a length longer than a length of the patients lumen, wherein no single graft member has sufficient mechanical strength to provide a desired amount of support to the lumen (graft members 152 of each component is made of the same materials as disclosed by the applicant-Dacron or ePTFE and of the thickness disclosed by the applicant, 0.1mm, which is between 0.002 and 0.008 inches, col.12, lines 5-20; thus inherently Marcade's graft members will have the same strength characteristics as the applicants graft members), the graft members configured to provide the sufficient strength over portions that are overlapped (col.18, lines 24-27). Marcade's graft members are configured to completely overlap (see for instance, fig.5; col.20, lines 15-25; other portions of the disclosure cite a "sufficient overlap" between members, col.16, lines 48-51; col.17, lines 1-2, 60-61). Marcade discloses anchoring mechanisms (stents 154 OR barbs 156) at the ends of the graft members. Marcade discloses the graft members to be individually delivered (abstract) by a low profile catheter system (300; fig.9-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 9-13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. (US 6,123,722, cited previously). Referring to claims 6 and 16, Fogarty discloses a layered endovascular graft (60, 90; fig.3-5; see above) having expansion capabilities on a catheter substantially as claimed (col.9, lines 24-29). Fogarty does not disclose however, the exact dimensions of the catheter diameter nor the compressed graft diameters. It would have been obvious for one having ordinary skill in the art at the time the invention was made to have the claimed dimensions since wherein the general conditions of a claim are disclosed in the prior art (graft members and a catheter having a shown diameter) it is not inventive to discover the optimum or workable ranges (3-40mm and 4mm). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 9-13, Fogarty discloses a method of deploying a graft comprising providing at least two thin graft members, delivering one through a catheter (30) and deploying the one, then delivering a second thin graft through a catheter (30) and deploying the second within a lumen of the first (fig.5a-5c; col.6 line 55-col.7 line 5). Fogarty has shown the inner graft (66 in fig.3) to extend longitudinally from an end of the outer graft (62; see fig.3). Although Fogarty does not specifically disclosed overlapping two graft members *completely* such that one is completely within the other, Fogarty does disclose controlling the overlap range of two graft members to tailor to the needs of the patient. Because Fogarty discloses variation of the overlap range, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a complete overlap, since such an overlap range seems to be disclosed by Fogarty already, and such an overlap range (complete) would provide the predictable results of increased seal and support.

Claims 6, 9-13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcade (US 5,683,449). Referring to claims 6 and 16, Marcade discloses a plurality of expandable graft components configured for delivery separately by a catheter. Marcade discloses or shows the graft members (col.9, lines 22-28; col.10, lines 3-5) and catheter (fig.9, 10) to have a diameter, however does not disclose the exact diameters claimed. It would have been obvious to have the claimed dimensions since wherein the general conditions of a claim are disclosed in the prior art (thin graft members and a catheter having a shown diameter) it is not inventive to discover the optimum or workable ranges (3-40mm and 4mm). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 9-13, Marcade discloses a method of delivering and deploying separate graft members individually and overlapping the members with a "sufficient overlap", (col.16, lines 48-51; col.17, lines 1-2, 60-61) and discloses one embodiment shown in fig.5 wherein member (600) completely overlaps member (114; col.20, lines 16-25). Marcade does not disclose however the inner second graft (114) to be completely with first graft member (600). Second graft (114) although completely overlapping first graft (600), it also additionally extends distally from member (600). It would have been obvious to one having ordinary skill in the art that the plurality of overlapping graft members (110, 112, 114, 116, 600) of Marcade be made of different lengths and be arranged at different overlaps, such that each kit is tailored to needs of the particular patient, to provide adequate repair. A stronger seal is created at the overlap portion and increased support.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738